



Site: San Francisco

# FDAMA STAKEHOLDER MEETING

APRIL 28, 1999

## Talking with Stakeholders About FDA Modernization

\*\*Your question/comments will become part of Docket Number: 99N-0386

Fax to: 1-888-361-4011 (on April 28 only)

Title (required) First Name (required) Last Name (required)  
☐ Dr. ☒ Mr. Michael Ong  
☐ Mrs. ☐ Ms.  
 Organization UC Berkeley

Stakeholder Group ☒ stakeholder group you represent

☐ Consumer ☐ Consumer Group ☐ Health Professional ☐ Industry ☐ Association ☒ Other

Center ☒ the center/product area your comments address

☐ Center for Biologics Evaluation and Research ☐ Center for Drug Evaluation and Research  
☐ Center for Devices and Radiological Health ☐ Center for Food Safety and Applied Nutrition  
☐ Center for Veterinary Medicine ☐ Office of Regulatory Affairs  
☒ FDA General

### Questions to Stakeholders

Please check the box next to the stakeholder question/s from the March 22, 1999, Federal Register notice which your question/comment addresses.

- ☐ 1. What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?
- ☒ 2. What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?
- ☐ 3. What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?
- ☐ 4. What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?
- ☐ 5. What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?
- ☐ 6. Additional Comments on FDA Modernization Efforts.

### YOUR COMMENT/QUESTION

Does the FDA have any specific plans to enhance postmarketing surveillance? In particular, I am interested in efforts to enhance timely and widespread reporting from the public at large (ex: Medwatch for health professionals)

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